

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparing efficacy and tolerability of lamotrigine and levetiracetam in elderly patient with diagnosed epilepsy

#### Protocol summary

##### Summary

Choosing the right drug with the least side effects and highest effectiveness for the control of epilepsy in the elderly population is important. This study compared the lamotrigine efficacy with levetiracetam in the management of epilepsy in the elderly. The patients with age more than 60y and one year history of epilepsy were enrolled in this study. The study was double-blind randomized clinical trial. Patients were divided randomly into two groups. Group I and Group II treated with treated with lamotrigine were Lvtyrastam. The follow up of patients were done in 2, 4, 8, 12 and 20 week after completion of treatment to assessment of number of epilepsy attack, abnormality of lab test and drug complication. The patients were exclude due to lack of follow-up, severe medical complications and death.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013021211560N3**

Registration date: **2013-05-18, 1392/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-05-18, 1392/02/28

##### Registrant information

##### Name

Tayeb Ramim

##### Name of organization / entity

Sina Trauma and Surgery Research Center, Tehran  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of Research, Tehran University of Medical  
Sciences

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2012-09-22, 1391/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing efficacy and tolerability of lamotrigine and  
levetiracetam in elderly patient with diagnosed epilepsy

##### Public title

Epilepsy management in elderly

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria : age>60 years old; one year diagnosis;  
two or more attack in the last year; one and more attack  
in 6 months ago; life expectancy more one year;  
unprovoked or generalized epilepsy; no history of  
lamotrigine and levetiracetam sensitivity and no history  
of mental disorder. Exclusion criteria: no tolerability to  
drug reaction; severe complication; lost to follow up;  
drug and alcohol abuse; low level of consciousness after  
drug use due to underlying disease and death.

##### Age

From **65 years** old to **100 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 95

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

**Street address**

Hemat gateway, Central division of Tehran University of Medical Sciences

**City**

Tehran

**Postal code****Approval date**

2011-09-23, 1390/07/01

**Ethics committee reference number**

827

**Health conditions studied****1****Description of health condition studied**

Elderly epilepsy

**ICD-10 code**

G40

**ICD-10 code description**

Epilepsy

**Primary outcomes****1****Description**

Epilepsy management

**Timepoint**

Four weeks after drug use

**Method of measurement**

Interview

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Lamotrigine was start in 25mg/day and continue to 200mg/day

**Category**

Treatment - Drugs

**2****Description**

Levetiracetam was start in 250mg/day and continue to 1000mg/day

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr. Pardis Etemadi

**Street address**

Sina Hospital, Imam Khomeini St, Hasan Abad Sq

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Deputy of Research, Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

**Street address**

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research, Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Sina Hospital, Tehran University of Medical Sciences

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*